CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75-547

Bioequivalence Review(s)

BIOEQUIVALENCY COMMENTS TO BE PROVIDED TO THE APPLICANT

ANDA: 75-547 APPLICANT: Bedford Laboratories

DRUG PRODUCT: Thiotepa for Injection
15mg/vial

The Division of Bioequivalence has completed its review and has no further questions at this time.

Please note that the bioequivalency comments provided in this communication are preliminary. These comments are subject to revision after review of the entire application, upon consideration of the chemistry, manufacturing and controls, microbiology, labeling, or other scientific or regulatory issues. Please be advised that these reviews may result in the need for additional bioequivalency information and/or studies, or may result in a conclusion that the proposed formulation is not approvable.

Sincerely yours,

Dale P. Conner, Pharm.D.
Director Division of Bioequivalence
Office of Generic Drugs
Center for Drug Evaluation and Research

Thiotepa for Injection
15 mg/Vial
ANDA #75-547
Reviewer: Andre Jackson
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Bedford Laboratories
Bedford, Ohio
Submission Date:
December 29, 1998

Review of Waiver Request

I. Background:

The firm has requested a waiver of the bioequivalence study requirements for its products Thiotepa for Injection, 15 mg/Vial. The innovator products are Thioplex® for Injection 15 mg/Vial and Thiotepa® for Injection 15 mg/Vial, manufactured by Immunex. The former product Thioplex® was approved as NDA 20058 while the latter was approved as Thiotepa® NDA 11683. The product Thiotepa® contains the inactive ingredients sodium chloride and sodium carbonate. The generic product is called thiotepa but is actually equivalent to Thioplex® which contains only the active ingredient thiotepa.

II. Formulations: **(Not to be released under FOI)**

The formulations of Bedford's thiotepa and Immunex's Thioplex® for Injection, 15 mg/Vial are shown in Table I.

--within the USP limit of 95-110% of the labeled amount

Comments:

1. The active and inactive ingredients and their concentrations for the test products are the same as those of the innovator's Thioplex® 15 mg/vial for Injection, manufactured by Immunex.

2. Waivers of in vivo bioequivalence study requirements may be granted based on 21 CFR 320.22(b)(1).

Recommendation:

The Division of Bioequivalence agrees that the information submitted by Bedford Laboratories, demonstrates that Thiotepa for Injection, 15 mg/Vial falls under 21 CFR 320.22 (b)(1). The waivers of in vivo bioequivalence study for the test products are granted. From the bioequivalence point of view, the Division of Bioequivalence deems the test injectable formulations 15 mg/Vial to be bioequivalent to Thioplex® 15 mg/vial Injectable, manufactured by Immunex.

The firm should be informed of the above recommendation.

Andre J. Jackson
Division of Bioequivalence
Review Branch I

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FT INITIALLED YHUANG Date: 2/22/99

Concur: Date: 2/23/99
Dale P. Conner
Director
Division of Bioequivalence

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